



May 3, 2005

Notification of statements on Dietary Supplement Labels

MAY 17 2005

Division of Compliance and Enforcement
Office of Nutritional Products, Labeling and Dietary Supplements
Food and Drug Administration
(HFS-810)
5100 Paint Branch Parkway
College Park, MD 20740-3835

Dear Sir/Madam:

Reference is made to Highly Potent PFO Pure Fish Oil plus Phytosterols and Lipase, marketed by Arkopharma, LLC.

Pursuant to Section 403(r)(6) of the Federal Food, Drug and Cosmetic Act, as codified in 21 U.S.C. 343(r)(6), notification is submitted for structure/function statements made on the following dietary supplement product.

Product Name: Highly Potent PFO Pure Fish Oil plus Phytosterols and Lipase

Ingredients: Fish oil concentrate, Phytosterol esters, Lipase

Company Name/ Address: Arkopharma, LLC
19A Crosby Drive
Suite 300
Bedford, MA 01730-1401

Text of Claims:

1. Phytosterols for added cardio support
2. Omega-3 Healthy Heart Maintenance
3. The enzyme lipase is added for optimum digestion and absorption.
4. provides higher potency omega-3 EPA and DHA nutrition in an innovative blend of fish oil plus phytosterols, natural plant compounds that help maintain cholesterol levels already in the normal range.
5. Heart-Healthy Omega-3

In accordance with 21 CFR 101.93, the disclaimer statement is bolded and boxed on all panels of the label where structure/function claims appear.

The undersigned certifies that the information contained in this notice is complete and accurate and that Arkopharma LLC has substantiation that the statement is truthful and not misleading.

As required, the original and two copies of this notification are enclosed. If you have any questions regarding this information, please contact the undersigned at (781) 276-0505.

Sincerely,

Barbara Levenstein, M.S.
Director of New Product Development
Arkopharma, LLC

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